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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,574	05/31/2007	Stig Bengmark	05822.0340USWO	8316
23552 7590 01/25/2008 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER ARIANI, KADE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 01/25/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/588,574	BENGMARK, STIG	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kade Ariani	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 1, and 3-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

***DETAILED ACTION***

The preliminary amendment filed on July 25, 200, has been received and entered.

Claims 1-13 are pending in this application and were examined on their merits.

***Claim Objection***

The disclosure is objected to because of the following informalities:

The word --fibers—in claim 1 is misspelled as “fibres”, also --fiber-- in claims 3-7, is misspelled as “fibre”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation a method according to claim 1 wherein ....the inflammatory disorder is...". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-13 are rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter.

Claims 1-13 are directed to a formulation comprising "*Pediococcus pentosaceus*, *Leuconostoc mesenteriodes*, *lactobacillus paracasei* subsp *paracasei*, and *Lactobacillus plantarum*" and a method of applying the formulation. *Pediococcus pentosaceus*, *Leuconostoc mesenteriodes*, *lactobacillus paracasei* subsp *paracasei*, and *Lactobacillus plantarum* are naturally occurring lactic acid bacteria and are not a "manufacture". The claims do not require any physical transformation of the lactic acid bacterial cells. The claimed invention would impermissibly cover every substantial practical application of, and thereby preempt all use of a product of nature.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (US 2003/0147857 A1) in view of Kruszewskya et al. (in IDS, Microecology and Therapy, 2002, Vol. 29, p.37-49) and further in view of Kaur et al. (European Journal of Pharmaceutical Sciences, 2002, Vol. 15, p.1-9) and further in view of Bengs et al. (US Patent No. 7,097,831 B1) and further in view of Zhang et al. (JBC, 2002, Vol. 277, p.46116-46122).

Claims 1-13 are drawn to a method for manufacturing a formulation for the treatment of stress-induced inflammatory disorder comprising providing *Pediococcus pentosaceus* 16:1, *Leuconostoc mesenteriodes* 32-77:1, *Lactobacillus paracasei* subsp *paracasei* F-19, and *Lactobacillus plantarum* 2362, wherein the bacterial strains are in an amount of at least  $10^{11}$  CFU/ml of each of the bacteria and at least four different fibers, and a method for treating a mammal suffering from a stress-induced inflammatory disorder comprising applying a formulation to the animal.

Monte teach a formulation and a method of manufacturing the formulation comprising providing probiotics and prebiotic, *Pediococcus pentosaceus*, *Lactobacillus paracasei*, and *Lactobacillus plantarum*, wherein the bacterial strains are in an amount of  $10^{10}$  or more of each of the bacteria, beta-glucan, inulin, pectins, vitamins, and a

method for treating a mammal comprising applying a formulation to the mammal, formulation in form of tablet or drink, and  $10^6$  or greater probiotic are introduced (Abstract, page 3 0025, 0028, 0030-0033, page 4 0046, and page 5 0050).

Monte does not teach *Leuconostoc mesenteriodes* 77:1, *L. paracasei subsp paracasei* F-19, *L. plantarum* 3259.. However, Kruszewskya et al. teach *Pediococcus pentosaceus* 16:1, *Leuconostoc mesenteriodes* 32-77:1, *lactobacillus paracasei subsp paracasei* F-19, and *Lactobacillus plantarum* (Abstract, page 41 Table 2.).

Kruszewskya et al. further teach the induction of pro-inflammatory cytokine, and anti-inflammatory properties of the above-mentioned LAB strains, and a method for selection and screening of Lactic acid bacteria (LAB) as probiotic strains (see Abstract and Material & Methods).

Monte does not teach, resistant starch. However, Bengs et al. teach resistant starch (RS) the concentration of the resistant starch in the solution can vary within a broad range, ( column 7 lines 29-31), and teach, resistant starch obtainable is suitable for use in medical preparations, in combination with other functional additives together with therapeutic agents (column 9 lines 1-5), other additives can be probiotics, (lactic acid bacteria), prebiotics, dietary fibers, vitamins antioxidants (column 5 lines 35-66).

Moreover, Kaur et al. teach that, it is a well-established fact that resistance to pathogens and an immune stimulation can be achieved by probiotic therapy. However, it is important that these probiotics reach the large intestine in an intact and viable form. Upon digestion, these probiotics are confronted by a number physical and chemical barriers, and one strategy is t to overcome such limitations of probiotics is the use of

non-digestible food ingredients that beneficially affect the host by selectively stimulation the growth and/or activity of one or a limited number of bacteria in the colon (page 7, 1st column last paragraph, and 2<sup>nd</sup> column 2<sup>nd</sup> paragraph).

Thus, one would have been motivated to add resistant starch to the formulation as taught by Monte in an attempt to improve the survival and implantation of live microbial dietary supplements.

Furthermore, Zhang et al. teach the role of myeloperoxidase (MPO) in the formation of bioactive lipid oxidation products and promoting oxidative stress during inflammation (see Abstract).

Therefore, it would have been obvious to one of the ordinary skill in the art to use LAB strains as taught by Kruszewskya et al. in the method of Monte and provide a formulation and a method for manufacturing and a method for treating a mammal suffering form a stress-induced inflammatory disorder (stomach inflammation) comprising applying to the mammal the formulation comprising. *Pediococcus pentosaceus* 16:1, *Leuconostoc mesenteriodes* 32-77:1, *lactobacillus paracasei* subsp *paracasei* F-19, and *Lactobacillus plantarum* 2362, and at least four different fibers. Since at the time the invention was made, the anti-inflammatory properties of LAB strains were known in the art, thus one would have been motivated to use those strains to treat inflammatory disorders. Moreover as taught by Kaur et al. it is important that these probiotics reach the large intestine in an intact and viable form, thus one would have been motivated to add resistant starch to the formulation as taught by Monte in an attempt to improve the survival and implantation of live microbial dietary supplements.



**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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